K093161

JAN 2 1 2011

2. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Diamedix Corporation
TRADE NAME:	MAGO 4S
COMMON NAME:	MicroChemistry Analyzer
CLASSIFICATION NAME:	Micro Chemistry Analyzer for Clinical Use
DEVICE CLASSIFICATION:	Class II, 866.3510 (Rubella virus serological reagents)
PRODUCT CODE	LFX (Enzyme Linked Immunoabsorbent Assay, Rubella) JJF
PANEL:	Virology (81)
PREDICATE DEVICES:	PhD System, Bio-Rad Laboratories (Class I, 510(k) exempt)

Note: The instrument performance assessment in this submission is based on both the performance data in the original Rubella submission (K981729) and the requested data described in the performance section below.

Description of the Device Subject to Premarket Notification:

The MAGO 4S is an automated laboratory instrument designed to automate the processing of enzyme-linked immunoabsorbent assays (EIA) as well as Immunofluorescence Assay (IFA) slides. The MAGO 4S is designed to minimize manual operations associated with performing routine laboratory analysis by mechanizing and computerizing the test process.

Intended Use:

For the qualitative, semi-quantitative and quantitative detection of IgG antibodies to rubella in human serum by indirect enzyme immunoassay to aid in the assessment of the patient's immunological response to rubella and in the determination of the immune status of individuals, including females of child-bearing age. The evaluation of acute and convalescent sera can aid in the diagnosis of current or recent infection with rubella.

The Mago 4S Automated EIA and IFA Processor is a pipetting, diluting, incubating, and color intensity analyzing system for *in vitro* diagnostic clinical use for the processing of FDA-cleared enzyme-linked immunoabsorbent assays (EIA) through result generation. In addition, it processes immunofluorescence assay (IFA) slides for off-platform detection and result generation.

Technical Characteristics:

The MAGO 4S Automated EIA and IFA Processor has similar physical and technical characteristics to the predicate device.

Basis for Determination of Substantial Equivalence:

Upon reviewing the information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the MAGO 4S Automated EIA and IFA Processor is determined by Diamedix, to be substantially equivalent to existing legally marketed devices.

Performance Data:

All necessary verification and validation testing has been performed for the MAGO 4S Automated EIA and IFA Processor to assure substantial equivalence to the predicate devices. Specifically the following tests were performed with Rubella IgG: Precision/ Reproducibility, Linearity/Reportable range (where the strong positive and weak positive samples were diluted seven times at evenly spaced intervals), Positive and Negative Agreement with Comparator and Assessment of Equivocal Zone, CDC Performance Panel, and the CDC Biological Standard.

1. Precision/Reproducibility: For Precision, there were 6 well characterized samples (Diamedix QC Panels) run; two were negative and the other four spanned the reportable range of the Diamedix test kit. Comparable results were obtained from testing these samples manually versus testing them on the MAGO 4S. For reproducibility, three positive normal samples were selected and diluted to adjust their value to be near 10 IU/ml (slightly positive), per the CLSI standard. Test results showed that 3 standard deviations of all data for each sample was < 3.0 IU/ml. See the tables on the following pages.

Site 1 Precision

Intra Assay CV %	Day	QC A Run 1	QC A Run 2	QC B Run 1	QC B Run 2	QC C Run 1	QC C Run 2	QC D Run 1	QC D Run 2	QC E Run 1	QC E Run 2	QC F Run 1	QC F Run 2
	1	47.14%	0.00%	20.20%	17.68%	0.74%	0.74%	0.52%	4.32%	0.44%	4.00%		0.29%
	2	23.57%	15.71%	10.88%	10.88%	0.70%	7.78%	1.50%	5.15%	9.21%	5.08%	0.00%	3.78%
	3	20.20%	15.71%	10.88%	17.68%	0.34%	0.28%	0.49%	1.59%	2.36%	5.31%	8.48%	
	4	0.00%	0.00%	20.20%	28.28%	3.45%	3.95%	4.49%	2.48%	7.44%	11.80%		2.58%
	5	0.00%	28.28%	10.88%	20.20%	8.60%	2.63%	6.46%	0.74%	3.50%	9.07%	1.45%	
	6	12.86%	0.00%	9.43%	28.28%	2.08%	6.30%	3.60%	4.67%	0.63%	4.63%		5.50%
	7	7.44%	0.00%	28.28%	47.14%	8.06%	2.55%	12.62%	4.51%	3.52%	2.47%		0.58%
	8	12.86%	10.88%	0.00%	15.71%	0.70%	18.00%	12.20%	8.19%	1.13%	3.25%	5.95%	3.87%
	9	20.20%	23.57%	0.00%	10.88%	1.76%	8.73%	11.76%	6.35%	4.73%	9.52%	1.02%	4.30%
	10	8.32%	15.71%	28.28%	38.57%	2.27%	0.60%	11.15%	2.52%	3.34%	3.79%		2.67%
	11	28.28%	47.14%	35.36%	20.20%	2.12%	2.97%	6.71%	8.20%	1.15%	0.66%		3.45%
	12	15.71%	15.71%	40.41%	32.64%	2.32%	1.08%	9.28%	10.26%	3.83%	0.38%		
	13	10.88%	8.32%	28.28%	10.88%	3.31%	5.13%	0.62%	10.41%	4.93%	3.81%		
	14	8.32%	9.43%	66.00%	23.57%	3.17%	2.02%	4.73%	3.43%	3.48%	3.03%		
	15	32.64%	7.44%	35.36%	15.71%	1.21%	2.34%	2.23%	4.16%	1.80%	0.64%		
	16	14.14%	10.88%	38.57%	23.57%	11.67%	6.69%	0.40%	14.36%	7.07%	10.88%		
	17	7.44%	0.00%	32.64%	12.86%	10.88%	8.55%	5.14%	0.47%	5.42%	1.46%	1.15%	4.19%
	18	0.00%	9.43%	9.43%	23.57%	0.63%	2.18%	4.70%	4.19%	6.42%	9.58%		
	19	32.64%	17.68%	0.00%	38.57%	3.01%	1.82%	11.90%	7.20%	5.47%	12.50%		3.63%
	20	0.00%	9.43%	0.00%	94.28%	0.71%	0.34%	2.26%	8.94%	0.22%	0.00%	0.45%	2.35%
Interassay Mean		0.668		0.624		22.853		30.308		35.104		47.649	
Interassay SD		0.230		0.189		3.423		3.799		3.881		1.945	
Interassay CV%		34.52%		30.32%		14.98%		12.54%		11.06%		4.08%	

Note: Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.
When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

Site 2 Precision

Intra Assay CV %	Day	QC A Run 1	QC A Run 2	QC B Run 1	QC B Run 2	QC C Run 1	QC C Run 2	QC D Run 1	QC D Run 2	QC E Run 1	QC E Run 2	QC F Run 1	QC F Run 2
	1	35.36%	40.41%	0.00%	60.61%	4.54%	5.33%	3.60%	6.04%	2.82%	2.74%		1.17%
	2	30.74%	22.33%	25.71%	60.61%	3.63%	8.67%	12.99%	6.61%	0.80%	1.60%		5.43%
	3	18.45%	62.85%	28.28%	25.71%	4.40%	3.11%	5.74%	5.13%	0.38%	6.03%	2.90%	1.01%
	4	18.45%	28.28%	26.19%	22.33%	5.01%	8.07%	9.12%	8.47%	0.84%	4.51%		
	5	22.33%	28.28%	28.28%	37.22%	13.42%	11.45%	9.90%	5.94%	4.49%	0.54%		1.88%
	6	35.36%	32.64%	106.07%	10.88%	3.45%	1.98%	9.76%	7.68%	2.47%	1.46%		
	7	20.20%	31.43%	17.68%	54.39%	8.55%	2.18%	6.38%	6.11%	0.39%	5.45%	0.87%	1.52%
	8	20.20%	42.43%	23.57%	47.14%	6.76%	3.37%	12.82%	3.35%	3.55%	1.13%		
	9	31.43%	33.67%	31.43%	30.74%	2.95%	3.21%	3.40%	10.17%	0.00%	2.23%		
	10	23.57%	25.71%	20.20%	31.43%	6.04%	0.47%	7.24%	10.24%		2.11%		
	11	30.74%	28.28%	43.89%	23.57%	1.39%	4.96%	5.24%	6.31%	1.37%	3.33%		
	12	30.74%	43.51%	21.76%	32.64%	7.58%	9.24%	23.13%	6.34%	2.05%			
	13	47.14%	18.45%	41.59%	58.23%	9.19%	8.79%	4.30%	11.74%	6.45%	0.68%	2.00%	2.23%
	14	30.74%	38.57%	35.36%	56.57%	6.07%	1.36%	5.39%	7.84%	1.10%	3.07%		0.00%
	15	18.45%	37.22%	20.20%	41.59%	0.00%	2.50%	13.83%	8.07%	2.29%	2.80%		
	16	23.57%	14.14%	47.14%	37.22%	6.50%	0.60%	2.93%	4.64%	6.22%	8.06%		0.00%
	17	16.97%	33.67%	28.28%	42.43%	1.59%	6.19%	2.54%	4.50%	0.90%	6.91%		
	18	30.74%	35.36%	47.14%	64.28%	5.19%	14.18%	5.10%	1.68%	1.70%	2.53%		2.33%
	19	10.88%	51.43%	47.14%	47.14%	14.52%	3.50%	6.98%	4.17%	1.53%	1.67%	0.16%	
	20	28.28%	16.97%	28.28%	0.00%	5.19%	9.95%	0.80%	2.72%	1.10%	3.47%	0.16%	0.15%
Interassay Mean		1.026		0.901		25.375		31.545		37.799		47.692	
Interassay SD		0.288		0.358		4.845		5.040		5.476		1.628	
Interassay CV%		28.11%		39.69%		19.09%		15.98%		14.49%		3.41%	

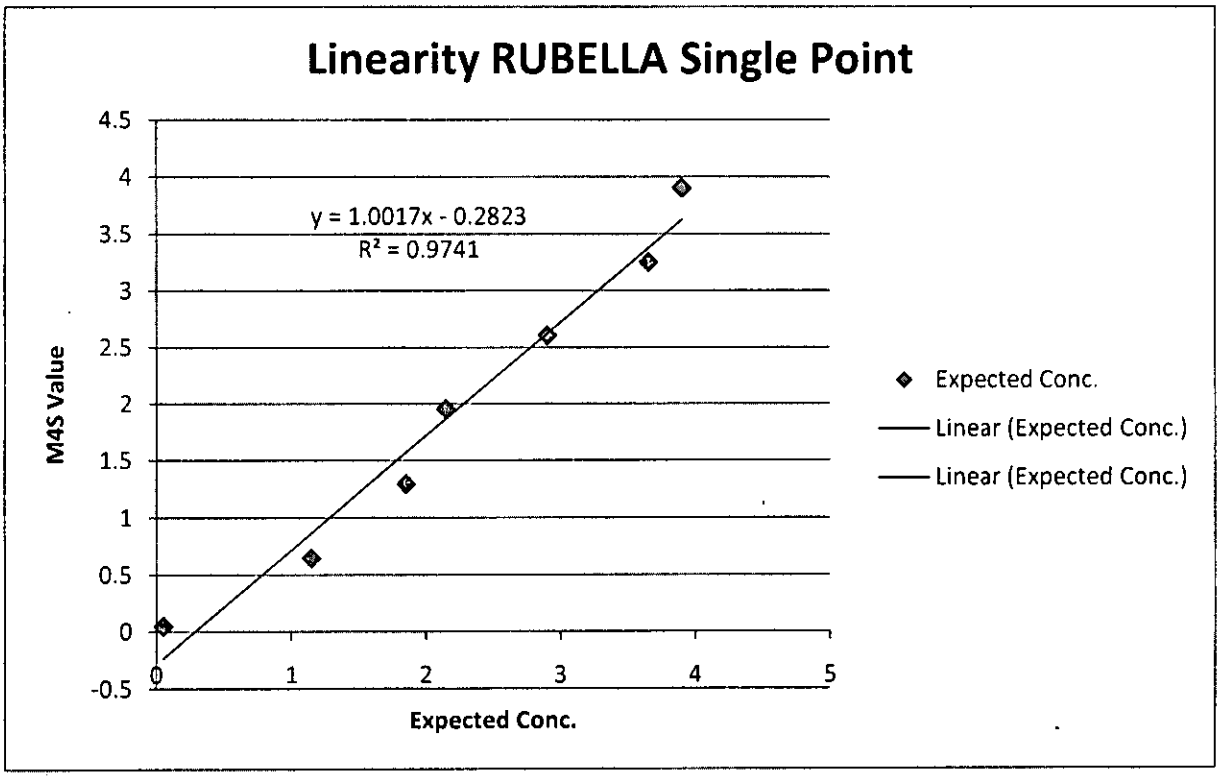
Note: Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.
When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)

Site 3 Precision													
Intra Assay CV %	Day	QC A Run 1	QC A Run 2	QC B Run 1	QC B Run 2	QC C Run 1	QC C Run 2	QC D Run 1	QC D Run 2	QC E Run 1	QC E Run 2	QC F Run 1	QC F Run 2
	1	0.00%	41.59%	47.14%	20.20%	21.49%	14.63%	0.23%	3.13%	5.19%	4.81%		2.42%
	2	31.43%	47.14%	28.28%	35.36%	0.66%	7.99%	1.58%	4.81%	1.27%	1.04%		
	3	53.03%	35.36%	41.59%	28.28%	14.59%	0.31%	2.08%	4.89%	2.63%	3.21%		
	4	35.36%	41.59%	35.36%	35.36%	11.24%	3.86%	2.59%	0.92%	1.00%	0.79%		
	5	30.74%	42.43%	37.22%	31.43%	4.07%	2.85%	8.86%	8.21%	1.78%	0.65%		
	6	40.41%	31.43%	8.32%	31.43%	17.65%	5.26%		18.06%	4.93%	0.94%		
	7	23.57%		25.71%		3.01%		29.86%		0.00%			
	8	35.36%	51.43%	38.57%	47.14%	8.12%	1.38%	9.91%	13.65%	8.35%	4.16%		2.46%
	9	6.15%	28.28%	64.28%	42.43%	12.75%	11.93%	6.04%	7.35%	5.61%	3.23%		
	10	42.43%	30.30%	37.22%	42.43%	5.22%	3.46%	4.09%	6.19%	6.36%	0.40%		
	11	38.57%	28.28%	53.03%	47.14%	0.00%	2.24%	3.88%	4.74%	1.26%	5.17%		
	12	64.28%	30.74%	42.43%	37.22%	4.99%	0.51%	3.84%	1.94%	0.17%	1.05%		
	13	24.38%	32.64%	66.99%	33.67%	1.09%	2.89%	3.59%	6.10%	2.58%	1.54%		
	14	41.59%	47.14%	31.43%	28.28%	1.86%	8.04%	11.88%	3.61%	7.79%	1.54%		
	15	38.57%	40.41%	47.14%	41.59%	0.98%	3.87%	7.34%	8.32%	3.93%	1.13%		
	16	37.22%	37.22%	52.10%	47.14%	24.87%	6.56%	7.44%	5.05%	2.56%	5.78%		
	17	47.14%	66.00%	22.33%	54.39%	8.13%	15.41%	3.26%	2.28%	0.20%	0.69%		
	18	47.14%	37.22%	28.28%	35.36%	0.56%	0.81%	8.15%	11.26%	3.36%	6.09%		
	19	30.00%	32.64%	6.15%	33.67%	7.44%	2.89%	14.22%	6.10%	12.41%	1.54%		
	20	40.41%	41.59%	0.00%	47.14%	8.94%	1.50%	5.77%	6.51%	2.38%	6.15%	6.59%	
Interassay Mean		1.036		0.877		25.086		32.538		36.863		46.964	
Interassay SD		0.368		0.276		3.970		5.013		4.365		1.527	
Interassay CV%		35.54%		31.45%		15.83%		15.41%		11.84%		3.25%	
Note:	Readings for QC F that were reported as >200 are shown as blanks, no statistics were possible.												
	When low results are reported on an analyte, a high coefficient of variation (CV) may result. (Taken from CAP survey)												

2. Linearity/Reportable range: the strong positive and weak positive samples were diluted seven times at evenly spaced intervals. The R^2 of the regression line came out to be 0.974. See data below and the next page.

Mago 4S Linearity Study
RUBELLA Single Pt Site - DMX

Name	M4S Conc.	Mean	Mean ordered	Expected Conc.
RUBLOW	0	0.05	0.05	0.05
A-02	0.1		1.15	0.6474
.417L/.083H	1.3	1.15	1.85	1.2948
A-04	1		2.15	1.95
.334L/.166H	2	1.85	2.9	2.6052
A-06	1.7		3.65	3.2526
.25L/.25H	2.1	2.15	3.9	3.9
A-08	2.2			
.166L/.334H	2.7	2.9		
A-10	3.1			
.083L/.417H	3.6	3.65		
A-12	3.7			
RUBHIGH	4.1	3.9		
A-14	3.7			



3. Positive and Negative Agreement with Comparator and Assessment of Equivocal Zone:

For Sensitivity and Specificity, approximately 100 samples in the <10 IU/ml range, 50 samples in the 10-20 IU/ml range, and 50 samples in the >20 IU/ml range were assayed. A total of two hundred and eight sera were tested once manually and once on the Mago 4S. The breakdown of Positive, Negative, and Equivocal results are seen in the Table below.

Comparison of Qualitative Results of Manual versus Mago 4S

Mago 4S / Manual	Positive	Negative	*Equivocal	Total
Positive	98	0	2	100
Negative	2	80	3	85
***Equivocal**	10	1	12	23
Total	110	81	17	208

* Equivocal results are excluded from calculations.

An assessment of Equivocal Zone was subsequently performed, and each kit was tested on the MAGO 4S and manually against the approximately 20 patient samples which were earlier identified in a retest zone (having originally tested manually between 7 and 13 IU/ml). The results showed that there was a single sample mean that indicated positive (≥ 10 IU/ml) on the manual test and indicated < 10 IU/ml on the Mago 4S. All the <10 IU/ml individual results fall within the product's equivocal range of 8 to < 10 IU/ml, which would cause a retest. See the Table on the next page.

Comparison of Mago vs. Manual for samples near equivocal range

		Predicate (manual)		
		≥10 (+)	<10	Total
New Test (Mago 4S)	≥10	17	0	17
	<10	1	2	3
	Total	18	2	20

Positive Percent Agreement	94.44%
Negative Percent Agreement	100.00%

4. CDC Performance Panel results: a total of 100 sera provided by the CDC were tested for the presence of rubella IgG antibodies on the MAGO 4S. The subsequent data was sent to the CDC for evaluation, and all of the results passed. See the Table below.

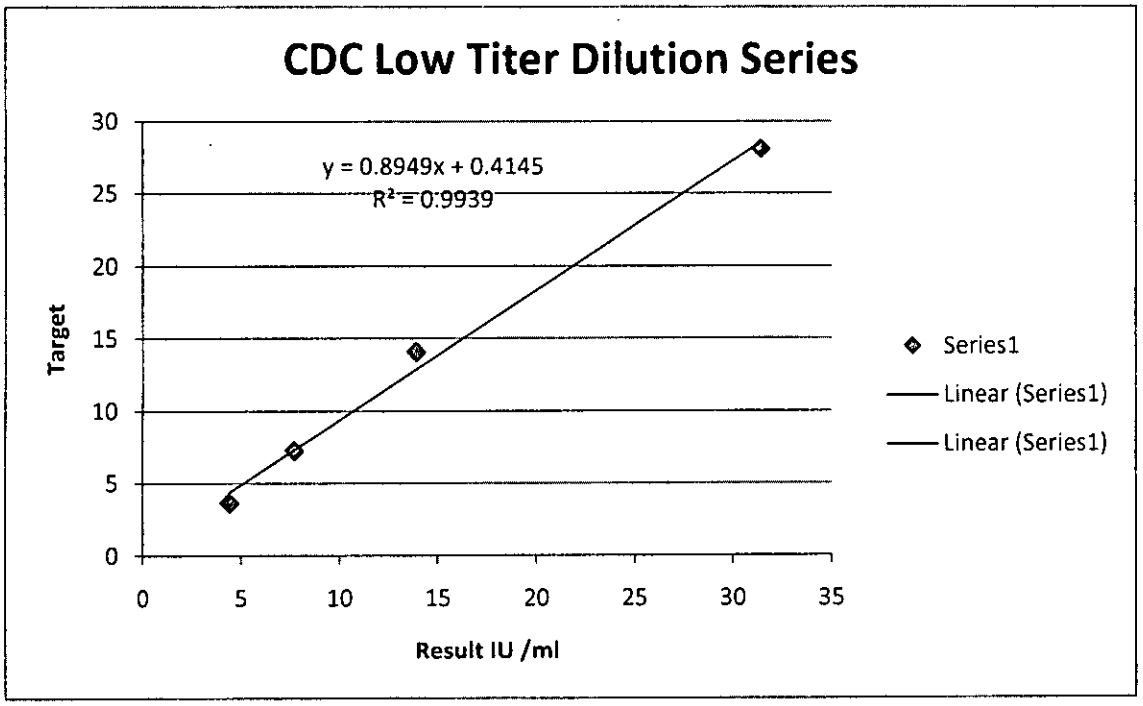
Summary of Evaluation of MAGO 4S Results of CDC Rubella serum panel

CDC Criteria	CDC Target	Results	Pass / Fail
Determination of Positive and Negative Sera	18 Neg / 82 Pos	18 Neg / 82 Pos	PASS
Reproducibility of results from paired sera	5 – 10 sera pairs with "bad ratios" (>1.25) (typical results)	Only 2 sera pairs with bad ratios; 39 sera pairs with "good ratios;" also, all 18 results from 9 negative sera pairs were negative	PASS
Correlation of DMX titer with HI titer of paired sera	No Major Deviations from continuously increasing signals for sera pairs	No Major Deviations from continuously increasing signals for sera pairs	PASS

5. CDC Biological Standard results: CDC Biological Standard, Low-Titer Anti Rubella Human Reference Serum, was used to verify the Diamedix Rubella IgG assay cutoff. This standard contains 21.0 IU/ml of Rubella IgG antibody. A dilution series was performed starting with a 1:2 dilution. The expected value for the 1:2 dilution of the CDC standard is 10 to 15 IU/ml, which is in agreement with the CDC immunity cutoff reference level. The results were within range as shown on the Table below and on the next page.

Low Titer CDC Control

	OD	IU/ml	Result	Target	Target - 10%	Target +10%
CDC 1:8	0.286	4.6	Neg			
CDC 1:8 Rep	0.277	4.4	Neg	3.625	3.2625	3.9875
CDC 1:4	0.424	7.3	Equiv			
CDC 1:4 Rep	0.443	7.7	Equiv	7.25	6.525	7.975
CDC 1:2	0.707	14.4	Pos			
CDC 1:2 Rep	0.69	13.9	Pos	14.05	12.645	15.455
CDC	0.951	24.8				
CDC Rep	1.033	31.4		28.1	25.29	30.91



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Diamedix Corp.
c/o Glenn Gerstenfeld
Director of Quality Assurance
Regulatory Affairs
2140 N. Miami Avenue
Miami, FL 33127

JAN 2 1 2011

Re: K093101

Trade/Device Name:	MAGO 4S
Regulation Number:	21 CFR §866.3510
Regulation Name:	Rubella virus serological reagents
Regulatory Class:	Class II
Product Code:	LFX, JJF
Dated:	December 1, 2010
Received:	December 2, 2010

Dear Mr. Gerstenfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

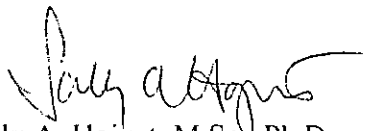
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093101

Device Name:

Indications for Use:

For the qualitative, semi-quantitative and quantitative detection of IgG antibodies to rubella in human serum by indirect enzyme immunoassay to aid in the assessment of the patient's immunological response to rubella and in the determination of the immune status of individuals, including females of child-bearing age. The evaluation of acute and convalescent sera can aid in the diagnosis of current or recent infection with rubella.

The Mago 4S Automated EIA and IFA Processor is a pipetting, diluting, incubating, and color intensity analyzing system for *in vitro* diagnostic clinical use for the processing of FDA-cleared enzyme-linked immunoabsorbent assays (EIA) through result generation. In addition, it processes immunofluorescence assay (IFA) slides for off-platform detection and result generation.

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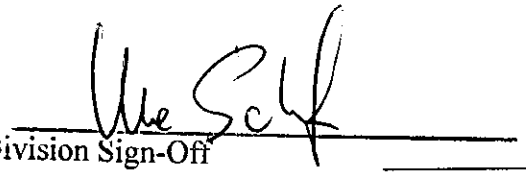
Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)



____X_____ Division Sign-Off _____

Prescription Use (Per 21 CFR 801. subpart D)

Office of In Vitro Diagnostic Device Evaluation and Safety

Over-The-Counter Use (Per 21 CFR 801. subpart C)

510(k) K093101